

REMARKS

Claims 1-5, 8-10 and 14-18 are pending. By way of the present amendment, new claims 19-23 are added and claims 1-5, 8-10 and 14-18 are cancelled without prejudice to or disclaimer of the underlying subject matter. Claims 6-7 and 11-13 were cancelled without prejudice to or disclaimer of the underlying subject matter in amendments filed October 14, 2003. Support for the foregoing new claims can be found throughout the specification and claims as originally filed, for example on page 12, line 14 through page 13, line 4 and page 35, line 9 through page 37, line 21. No new matter enters by way of this amendment. Upon entry of the foregoing amendment, claims 19-23 will be pending.

1. Request for Continued Examination

The instant application was appealed to the Board of Patent Appeals and Interferences ("Board") on March 31, 2004. The appeal was suspended at the request of the Applicants on March 24, 2005, pending the U.S. Court of Appeals for the Federal Circuit's disposition of *In re Fisher*. Applicants file herewith a Request for Continued Examination under 37 C.F.R. § 1.114.

2. Claim Rejections – 35 U.S.C. § 101

Claims 1-5, 8-10 and 14-18 stand rejected under 35 U.S.C. § 101, because the claimed invention is allegedly not supported by either a "specific, substantial, and credible utility or, in the alternative, a well-established utility." Final Action at pages 2-3. Although the specification describes multiple utilities for the present invention, the

Examiner asserts that “Applicant’s gene does not belong in a specific class of genes; and the use set forth is not deemed to be sufficiently substantial such that one skilled in the art can readily use the invention in a real-world sense.” *Id.* at page 2. Although Applicants disagree, to facilitate prosecution, claims 1-5, 8-10 and 14-18 have been cancelled without prejudice to or disclaimer to the underlying subject matter. However, Applicants respectfully submit that new claims 19-23 satisfy the 35 U.S.C. § 101 utility requirement.

The Federal Circuit has recently reiterated that the “basic *quid pro quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived from the public from an invention with *substantial utility*.” *In re Fisher*, 421 F.3d 1365, 1371, 76 U.S.P.Q.2d 1225, 1229 (Fed. Cir. 2005)(citing *Brenner*, 383 U.S. at 534-35)(emphasis in original). The Court noted that since “*Brenner* our predecessor court, the Court of Customs and Patent Appeals, and this court have required a claimed invention to have a specific and substantial utility to satisfy § 101.” *Id.* Furthermore, an invention need only provide one identifiable benefit to satisfy 35 U.S.C. § 101. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983) (“when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown”).

Although the Supreme Court has not defined the meaning of the terms “specific” and “substantial”, the Federal Circuit has identified a framework for the kind of disclosure an application could contain to establish a specific and substantial utility. *In re Fisher*, 421 F.3d at 1371, 220 U.S.P.Q.2d at page 1230. First, the Court indicated that to provide a substantial utility, the specification should disclose a utility such that “one skilled in the art can use a claimed discovery in a manner which provides some

immediate benefit to the public." *Id.* (emphasis original). Second, a specific utility can be disclosed by discussing "a use which is not so vague as to be meaningless," that is that the claimed invention "can be used to provide a well-defined and particular benefit to the public." *Id.*

Applicants have met this test – the present specification discloses nucleic acid molecules which, in their current form, provide at least one specific benefit to the public, for example, use for reducing expression of an endogenous gene. *See, e.g.* Specification at page 35, line 9 through page 37, line 21. The present specification discloses that the claimed nucleic acid molecules can be used to transform plants (*see, e.g.*, specification at page 21, line 4 through page 34, line 22); and to reduce the expression of a desired protein (*see, e.g.*, specification at page 35, line 9 through page 37, line 21). This benefit is specific, not vague or unknown, and it is a "real world" or substantial benefit.

The Examiner has not provided any evidence that would reasonably suggest that the claimed nucleic acids cannot be used for the aforementioned utilities, and therefore has not met the burden of proof required to establish a utility rejection. *See In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). *Accord In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *In re Langer*, 503 F.2d 1380, 1391, 183 U.S.P.Q. 288, 297 (C.C.P.A. 1974). In fact, the Examiner has provided no evidence challenging the disclosed utilities for the presently claimed nucleic acid molecules. The Examiner "must do more than merely question operability - [she] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 706.03(a)(1) ("Office

personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided..."). In the Office Action, the Examiner provides no evidence challenging the disclosed utilities for the presently claimed nucleic acid molecules.

The Examiner further has not assessed the credibility of the presently asserted utilities. Credibility is precisely the issue that the courts have emphasized in evaluating the adequacy of an asserted utility. Utility is determined "by reference to, and a factual analysis of, the disclosure of the application." *In re Ziegler*, 992 F.2d 1197, 1201, 26 U.S.P.Q.2d 1600, 1603 (Fed. Cir. 1993), *quoting Cross v. Iizuka*, 753 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985). The Examiner "has the initial burden of challenging a presumptively correct assertion of utility in the disclosure." *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *Id.* As previously stated, the Examiner "must do more than merely question operability – [she] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1224-25, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 706.03(a)(1) ("Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided..."). Here, the Examiner has not even attempted to meet this burden.

Applicants have disclosed several specific, substantial and credible utilities for the claimed nucleic acid molecules, for example, for reducing expression of an endogenous gene. Any one of these utilities is enough to satisfy the requirements of 35 U.S.C. § 101. Because Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so in the present case, the rejection under Section 101 is incorrect. Reconsideration and withdrawal of this rejection are respectfully requested.

3. Rejection under 35 U.S.C. § 112, first paragraph, Enablement

Claims 1-5, 8-10 and 14-18 stand rejected under 35 U.S.C. § 112, first paragraph as not enabled because the claimed invention allegedly lacks utility. Final Action at page 3. Applicants respectfully traverse this rejection and contend that this rejection has been overcome by the arguments set forth above regarding utility. Thus, the enablement rejection under 35 U.S.C. § 112, first paragraph is improper. As claims 1-5, 8-10 and 14-18 have been cancelled without prejudice to or disclaimer of the underlying subject, Applicants respectfully submit that the rejection of claims 1-5, 8-10 and 14-18 is moot. In addition, for the reasons set forth above with regard to utility, new claims 19-23 are enabled.

4. Rejection under 35 U.S.C. § 112, second paragraph

Claims 1-5, 8-10 and 14-18 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite. According to the Examiner, the terms “substantially purified” and “structural nucleic acid molecule” render the claims indefinite. Final Action at page 4. The Examiner’s position is unfounded.

It is axiomatic that claims are always construed in light of the specification, of which they are a part. *Networld L.L.C. v. Centraal Corp.*, 242 F.3d 1347, 1352, 58 U.S.P.Q. 2d 1076, 1079 (Fed. Cir. 2001); *Slimfold Mfg. Co. v. Kinkead Indus., Inc.*, 810 F.2d 1113, 1118, 1 U.S.P.Q. 2d 1563, 1566 (Fed. Cir. 1987). The test for determining whether terms in a given claim are indefinite is whether one skilled in the art would understand what is claimed. *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991), *cert denied*, 112 S.Ct. 169 (1991). A person of ordinary skill in the art would understand the metes and bounds of the claims read in light of the disclosure of the specification.

The specification delineates the scope of the claims such that one of ordinary skill in the art, *e.g.*, a molecular biologist, would understand what Applicants regard as the invention.

The Examiner asserts that the definition for “substantially purified” given in the specification is circular in that Applicants defines “substantially purified” as a molecule separated from substantially all other molecules normally associated with it. Office Action mailed July 16, 2003. A definition given in the specification should not be read in a truncated form and taken out of its context. The specification provides that “the term ‘substantially purified’... refers to a molecule separated from substantially all other molecules normally associated with it in its native state.” *See*, specification at page 8, lines 20-21. Applicants submits that when read in its entirety, “substantially purified” is defined in a manner free of circularity or indefiniteness.

Claims 1-5, 8-10 and 14-18 stand rejected as allegedly indefinite in the recitation of "structural nucleic acid." Final Action at page 4. Applicants respectfully disagree. Applicants respectfully point out that the claims are to be read in light of the specification. *See In re Vogel*, 422 F.2d 438, 441, 164 U.S.P.Q. 619, 622 (C.C.P.A. 1970). The test for determining whether terms in a given claim are indefinite is whether one skilled in the art would understand what is claimed. *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991), *cert. denied*, 112 S. Ct. 169 (1991). Furthermore, "[t]he mere fact that a term or phrase used in the claims has no antecedent basis in the specification disclosure does not mean, necessarily, that the term or phrase is indefinite. There is no requirement that the words in the claim must match those used in the specification disclosure." MPEP § 2173.05(e).

The specification describes, for example, the use structural nucleic acid molecules in the transformation of plants and in hybridizations. *See, e.g.*, Specification at page 3, lines 10-12, page 5 line 12 through page 6 line 5 and page 8, lines 15-20. Furthermore, claim 8 recites "a structural nucleic acid molecule encoding a protein comprising an amino acid sequence of SEQ ID NO: 45...." A person skilled in the art, reading the specification and the claims as a whole, would readily understand the phrase "structural nucleic acid." As such, the phrase "structural nucleic acid" satisfies the requirements of 35 U.S.C. 112, second paragraph and the rejection should be reversed.

Although Applicants disagree that claims 1-5, 8-10 and 14-18 are indefinite under 35 U.S.C. § 112, second paragraph, to facilitate prosecution, claims 1-5, 8-10 and 14-18 have been cancelled without prejudice to or disclaimer of the underlying subject matter.

As such, the rejection of claims 1-5, 8-10 and 14-18 for alleged indefiniteness is moot.

Conclusion

In view of the foregoing remarks, Applicants respectfully submit that the present application is now in condition for allowance, and notice of such is respectfully requested. The Examiner is encouraged to contact the undersigned at (202) 942-5000 should any additional information be necessary for allowance.

Respectfully submitted,



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